HEALTH PURCHASING VICTORIA

Invitation to Supply

Part 5 - Statement of Requirements

Invitation to Supply Number:	**HPVITS2019-079**
Invitation to Supply Name:	**Intravenous Access Devices and Administration Consumables**
HPVITS2019-079 Closing Date and time:	**Wednesday 19 September 2018, 14:00 AEST**

Authorised Contact Person

David Nguyen

Category Officer

Contact through the HPV Procurement Portal

https://www.hpv.org.au/

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A Introduction

1 Purpose

a. The purpose of this Part 5 - Statement of Requirements, is to:

(i) detail the scope and range of products sought under this Invitation to Supply (ITS); and
(ii) specify the requirements that Respondents and / or their offered products must meet. (these requirements also form part of any resulting Agreement between Health Purchasing Victoria (HPV) and any successful Respondent).

2 Scope

a. HPV is seeking responses for Intravenous Access Devices and Administration Consumables products for use in Participating Health Services (PHS). The envisaged term of the agreement is four (4) years plus one optional two (2) year extension period.(i.e. 4+2).

b. The scope of this ITS includes:

(i) the supply of Intravenous Access Devices and Administration Consumables products covered in section Part5-D2 Category Specification (standard purchases service requirements).

c. The scope of this ITS does not include the following:

(i) Supply of Long-term Haemodialysis Catheters;
(ii) Supply of Pharmaceutical products used in conjunction with Closed System Transfer Devices (CSTD);
(iii) Supply of CSTDs and associated consumables for pharmaceutical compounding by a third-party on behalf of a Participating Health Service; and
(iv) Supply of products that are currently in other active HPV Contracts.

3 Product Categories

a. A full list of product categories and subcategories can be found in Appendix 1 - Product List.

b. The Respondent may offer products in one, some or all categories.

c. Only products that specifically fit within the category specification provided will be considered.

d. Preference to offers with the greatest range and best value for money across and/or within product categories (with the exception of niche product ranges) may be given.

e. HPV reserves the right not to consider any additional products offered.

4 Product Conditions

4.1 Clinical Trials

a. Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

4.2 Product Duplication

a. HPV will not consider any product that is subject to a current HPV Agreement.

b. The Respondent must ensure that each product is offered in only **one** subcategory.

c. It is at the Respondent's discretion to ensure that each product is submitted in the most appropriate subcategory.

4.3 Product Information

a. The Respondent must submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

b. Where research papers or relevant scientific information is available, this should be submitted with the Respondent's tender.

c. All product information submitted should:

(i) be in electronic format;
(ii) be in English;
(iii) be specific to the product offered;
(iv) contain the Respondent's company name;
(v) include the product code;
(vi) include a detailed specification of the product; and
(vii) include clear diagrams/pictures of the product.

d. To assist in managing this material, all product information submitted must be labelled with the relevant HPV category and subcategory number, and TGA code where applicable.

Electronic copies must include the HPV Category and subcategory numbers in the filename or identifying metadata.

HPV may not consider unlabelled submissions.

e. Product information will not be evaluated, but is necessary to assist in accurately identifying products offered.

f. HPV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per Part 5 section D; or
(ii) Is incomplete as to Part 5 section C.

g. The Respondent should not submit information relating to products that are not called for in this ITS.

h. Respondents are to provide for evaluation purposes samples of submitted products and accessories. For products currently on the HPV contract, no samples are required. Sample provided should include:

(i) one (1) sample of one (1) size for each product type of each range or sub-category;
(ii) single use or re-usable;
(iii) sterile or non-sterile;
(iv) a list of all samples provided; and
(v) instructions for use, where applicable.

i. All samples provided should be:

(i) new and unopened;
(ii) packed, sealed and labelled; and
(iii) include supporting specifications and relevant data.

j. Each sample submitted should be clearly labelled with the following information:

(i) name of the Respondent;
(ii) ITS name and number;
(iii) name and number of the sub-category that the product has been tendered into; and
(iv) product code and description.

k. All samples submitted will be disposed of upon completion of the evaluation process unless collection or return instructions are supplied with each sample. Samples to be returned will be at Respondent's cost.

l. For samples to be returned, Respondents are to include instructions with the samples with the following:

(i) clear instructions to indicate if the samples are to be collected from HPV or are to be sent back at the Respondent's cost. For samples that are to be sent back, instructions are to include the freight account or 'con note', an address print out and any necessary paperwork that is to be used by HPV to enable the return to occur.

m. Samples are to be sent to the following address:

Attention to: David Nguyen
HPVITS2019-079
Health Purchasing Victoria
Level 34, Casselden Place, 2 Lonsdale Street
Melbourne, VIC 3000

n. All samples are to arrive at the above address before the Tender Closing Date and Time, unless otherwise stated.

5 Definitions

a. For the purposes of this tender, the following terms shall adopt the given definitions.

TERM	DEFINITION
Agreement	A contract entered into by HPV and a Respondent for the provision of goods and associated services. Comprises of the General Conditions, and all Schedules, Annexures of any kind and any attachments.
Atms	Atmospheres.
ARTG	Australian Register of Therapeutic Goods under the control of TGA
Business day	Any weekday not gazetted as a public holiday in Melbourne, Victoria.
Consumable (single use)	Intended to be discarded after one use
DEHP	Diethylhexyl phthalate. One of the most commonly used plasticisers in flexible PVC. CAS number: [117-81-7]
GS1	Global Standards One
GTIN	Global Trade Identification Number
HPV	Health Purchasing Victoria
Integral	Used to indicate that a component is built-in to a device (i.e. it cannot be removed). For example, '*integral access port*' means that the access port is an essential component and is built-in to the device.
ITS	Invitation To Supply
May	Indicates an optional element; it is at the Respondent's discretion to either meet or not meet this element, and failure to meet this element will not have an impact during evaluation.
Must	Indicates a mandatory requirement; failure to meet this requirement will have a significant negative impact during evaluation.
Needleless luer access	For the following categories: **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.**, a device that has closed and/or open luer access with a luer connection.

TERM	DEFINITION
Non-safety	For the following categories: **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.**, a device *without* a built-in safety mechanism to prevent accidental needle stick injuries.
NPC	National Product Catalogue.
OEM	Original Equipment Manufacturer.
Participating Health Services (PHS)	Public Hospitals and other Health or Related Services, as those terms are defined in Section 3 of the Health Services Act 1988 (Vic), that are described in Appendix 5 of Part 8.
PSI	Pounds per Square Inch.
Respondent	Any person, company or organization representing to this ITS and, unless the context otherwise requires, includes those who may access the ITS for the purpose of submitting a Tender.
Reusable	Able to be used again or more than once.
Safety	For the following categories: **Error! Reference source not found.** **Error! Reference source not found.** **Error! Reference source not found.**, a device *with* a built-in safety mechanism that is designed to prevent accidental needle stick injuries.
Shelf life	The date indicator listed on products, whether it is listed as Best Before, Use By or another term.
Should	Indicates a highly desirable element; unless justifiable reason exists, not meeting this element may have a medium impact during evaluation.
Single use	A device that is intended to be used on an individual patient, during a single procedure, and then discarded.
Single patient use	A device that is intended to be used on an individual patient.. (Source: TGA, Regulation of the Re-Manufacture of Single Use Medical Devices).
SLA	Service Level Agreement.
TGA	Therapeutic Goods Administration.
TRW	Tender Response Worksheet.
Will	Indicates an anticipated future condition or requirement.

B Service, Delivery and Support

1 Delivery

a. Intravenous Access Devices and Administration Consumables must be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed two (2) business days from receipt of order unless otherwise agreed with the Participating Health Service.

b. All deliveries are bound per the Draft Agreement, Part 7 – 11 Acceptance and Rejection of Deliverables.

2 Urgent Deliveries

a. For the purposes of this section, urgent deliveries refers to urgent requests placed by an individual Participating Health Service, and does not include state-wide emergency situations.

b. Respondents are to be able to receive and action urgent deliveries.

c. Urgent deliveries should be received by Participating Health Services within the shortest possible timeframe. This should be within **24 hours** from the receipt of order.

3 Training

a. Upon request by a Participating Health Service, successful Respondents must deliver a training package and/or training materials, at no cost to participating health services, to the clinicians in their hospital environment. This is to facilitate the introduction of their Intravenous Access Devices and Administration Consumables contract.

b. Training requirements may include (but are not limited to):

(i) face-to-face training at Participating Health Service sites (i.e. in-service training);
(ii) off-site study days for clinicians;
(iii) updates and refresher training on new products and/or equipment and surgical techniques; and
(iv) training materials.

c. If requested by a PHS, successful Respondent must provide an education plan detailing how they will provide training to nominated staff. Note that the number of staff involved in training may vary greatly between PHS.

d. Successful Respondent must ensure that the following is available to PHS (in either hard-copy or electronic format):

(i) the credentials of any staff who would be providing support in Victoria;
(ii) the hours of availability for support;
(iii) the geographical area covered by the support (if support is available on-site); and

(iv) the details of educational and/or support materials available to clinicians.

e. All training regimes must be implemented and include appropriate levels of training to meet Workplace Health & Safety standards as required by The Victorian WorkCover Authority.

4 Customer Service and Support

a. The successful Respondent must be able to deliver prompt customer service and support to Participating Health Services.

b. The successful Respondent will nominate at least one Representative as the key account manager to provide the support and to work closely with the PHS and HPV.

c. The successful Respondent will provide Participating Health Services with representatives that are:

(i) inherently familiar with the contracted products;
(ii) appropriately qualified;
(iii) technically/clinically knowledgeable about the contracted products;
(iv) available to respond to Participating Health Services' queries during business hours; and
(v) representatives are required to have a valid Police Check and will require a Working with Children Check for the Health Services' that treat children.

d. It is desirable that nominated Representatives have a clinical background or experience.

e. The level of customer service and support required of Representatives is expected to include (but is not limited to):

(i) liaising with clinicians to recommend products and solutions;
(ii) promptly answering clinicians' queries;
(iii) liaising with various hospital departments (for example: operating theatre, Infection Prevention Manager, Supply Managers);
(iv) providing on-site clinical support during cases (if requested);
(v) providing informational materials; and
(vi) providing education and in-service training upon request.

5 Warranty

a. All reusable products covered in this ITS are to be warranted for a minimum of twelve (12) months from the delivery date for normal use.

b. All consumable (single patient use) products are to be warranted for the duration of the recommended single patient use period or 12 months, whichever is the shorter, or for the recommended number of single patient use instances.

c. Where unopened, all consumable (single use) products are to be warranted up to the marked up expiry date. Where opened, all consumable (single use) products are warranted to be free of defects and fit for purpose.

d. Upon request, the successful Respondent must provide information (printed or electronic) explaining product warranty in plain language.

e. It is desirable that the Products can be used with the manufacturer's and non-manufacturer's equipment and software, and that the manufacturer's warranty is not adversely impacted.

Repairs and Replacements under Warranty

f. The repair or replacement of any item under warranty will be at no cost to the Participating Health Service.

g. The cost of any pickup or delivery associated with a repair or replacement under warranty will be borne by the successful Respondent.

h. It is highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

6 Service Level Agreement

a. Successful Tenderers shall enter into a Service Level Agreement (SLA) with individual contract users upon request. The SLA shall cover arrangements including, but not limited to:

(i) requirements for stock management and rotation;
(ii) arrangements for ordering, invoicing and delivery;
(iii) clinical support, including attendance requirements for representatives, education and training; and
(iv) communication arrangements for product recall and safety alert information.

b. The SLA will be in addition to the Agreement between a successful Tenderer and HPV, and will not alter any terms of the Agreement.

c. HPV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.

d. Successful Respondent(s) will provide a copy of all Service Level Agreements to HPV within 1 week of being finalised.

C General Requirements

1 Standards and Compliance

a. All items offered must comply with relevant Australian Standards (or their equivalent International Standards). Refer to **Error! Reference source not found.Error! Reference source not found.** for a list of the minimum relevant standards.

b. All items offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response.

c. The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

Latex Content

d. In the relevant columns of the Tender Response Worksheet, Tenderers shall identify the presence of natural rubber latex in each product tendered (including any accompanying packaging).

Preference will be given to items that are latex-free, unless otherwise stated.

DEHP Content

e. In the relevant column of the Tender Response Worksheet, Tenderers shall identify the presence of DEHP for each product tendered.

HPV is committed to providing DEHP-free product options in each category, wherever possible.

2 Packaging and Labelling

a. Products must be packaged to retain the structural integrity of the enclosed product.

b. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

c. Packaging must protect products with sharp points or edges (e.g. needles, where present) and be safe when packages are handled.

d. All labels must comply with the Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods.

e. Items will be delivered in accordance with the manufacturer's instructions.

f. It is a requirement for individual product packaging to include (where applicable):

(i) Whether all components of the product are sterile or stipulating any non sterile components or parts of the kit pack;
(ii) whether the product is MRI compatible (implantable products);
(iii) whether the product (or packaging) contains latex or is latex-free; and
(iv) tracking labels.

3 Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (2004).

b. Within six (6) months of contract commencement, all recalls and/or hazard alerts will be completed using GS1 Recallnet.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods*) must also meet the requirements under section Part 5 - B4a The successful Respondent must be able to deliver prompt customer service and support to Participating Health Services.

d. The successful Respondent will nominate at least one Representative as the key account manager to provide the support and to work closely with the PHS and HPV.

e. The successful Respondent will provide Participating Health Services with representatives that are:

(i) inherently familiar with the contracted products;
(ii) appropriately qualified;
(iii) technically/clinically knowledgeable about the contracted products;
(iv) available to respond to Participating Health Services' queries during business hours; and
(v) representatives are required to have a valid Police Check and will require a Working with Children Check for the Health Services' that treat children.

f. It is desirable that nominated Representatives have a clinical background or experience.

g. The level of customer service and support required of Representatives is expected to include (but is not limited to):

(i) liaising with clinicians to recommend products and solutions;
(ii) promptly answering clinicians' queries;
(iii) liaising with various hospital departments (for example: operating theatre, Infection Prevention Manager, Supply Managers);
(iv) providing on-site clinical support during cases (if requested);
(v) providing informational materials; and
(vi) providing education and in-service training upon request.

h. Warranty, where applicable.

4 Backorders and Discontinued Lines

a. In the event that a product is unavailable for a period of two or more consecutive weeks, the successful Respondent must contact (at a minimum) the following:

(i) Procurement Officers of all Participating Health Services;
(ii) Supply Manager / Business Managers of all Participating Health Services;
(iii) Clinical Product Advisers, where applicable; and
(iv) HPV.

b. In the event that an item is discontinued, successful Respondents must notify Participating Health Service staff and HPV (as per clause a) as soon as possible, but no less than six (6) months before the last date of manufacture.

c. Successful Respondents must inform the affected Participating Health Services and HPV of:

(i) the anticipated timeframe for resolving the issue;
(ii) a backorder report and a list of recommended substituted items (where applicable) to the Participating Health Services and HPV for reference; and
(iii) the availability of an agreed substitute product.

5 Infection Control

a. Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

b. Documentation and reprocessing instructions relevant to Australian standards AS/NZS 4187 are to be provided by successful Respondents to the Participating Health Services if supplying products and instruments that can be reusable.

6 Superseded Products

a. Where a contracted item is superseded, the new product shall be offered at the price of the original contracted item. This change request must be submitted to HPV for approval through HPV's Contract Variation process.

7 Shelf Life

a. Products that have an Expiry Date (where applicable) are to have a minimum of six (6) months shelf life on delivery to all PHS.

8 Reference Sites

a. Respondent are required to provide a minimum of three (3) Australian clinical references that are purchasing or have trialled and evaluated the product offered in this submission.

b. Where a product category contains a variety of specific sub-categories, Respondent are to ensure that the clinical references provided are representative of the full range of products tendered.

c. HPV reserves the right to verify this information with health services personnel and seek user feedback as to the acceptability of these products.

d. Respondent should not nominate a referee without their express permission.

D Product Specifications

1 Product Specification and Product List

a. Tenderers should note that this tender does not include intravenous pump administration sets. Pump administration sets are part of the Infusion Pumps contract: HPVC2016-55.

b. Preference may be given to products that are free of phthalate content, particularly diethylhexyl phthalate (DEHP) and are latex free.

2 Category Specifications

a. A range of Intravenous Consumables is required for treatment of patients across Victorian Public Health Services.

b. Products offered with optional components are to comply with the specifications for other relevant categories (where applicable).

Category 1 - Peripheral Intravenous Cannulae

A range of sterile, kink-resistant peripheral intravenous cannulae is required for the administration of intravenous therapy.

Mandatory Criteria

All peripheral intravenous cannulae offered shall be radio-opaque.

Product Description

For each peripheral intravenous cannula offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- safety or non-safety;
- passive or active (where applicable); and
- cannula:
  - gauge;
  - length, in millimetres;
  - material of construction (e.g. polyurethane);
  - securement features (where applicable) (e.g. winged);
  - with or without extension tubing; and
  - any additional features, such as an integral access port.

- extension tubing (where applicable):
  - diameter, in millimetres;
  - length, in millimetres;
  - straight or Y-ports;
  - type of clamps (e.g. slide or pinch);
  - integral access ports:
    - brand name;
    - number of ports; and
  - number of port caps (where applicable).

Additional Information

For each peripheral intravenous cannula offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- priming volume of extension tubing, in millilitres (where applicable);
- whether the peripheral intravenous cannula is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second.
  - the recommended number of power injection
- whether the peripheral intravenous cannula is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 2 - Winged Intravenous Devices

A range of sterile, winged intravenous devices is required for the administration of intravenous and subcutaneous therapy.

Tenderers note

This category does not include winged infusion devices with integral adaptors for evacuated blood collection. These devices are situated in the Pathology Consumables contract: HPVC2017-042.

Mandatory Criteria

All winged intravenous devices offered shall be radio-opaque.

Product Description

For each winged intravenous device offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- safety or non-safety;
- cannula:
  - gauge;
  - length, in millimetres;
  - material of construction;
  - with or without extension tubing.
- extension tubing:
  - diameter, in millimetres;
  - length, in millimetres;
  - straight or Y-ports;
  - type of clamps (e.g. slide or pinch);
  - integral access ports (where applicable):
    - brand name;
    - number of ports.
  - number of port caps (where applicable).

Additional Information

For each winged intravenous device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- priming volume of extension tubing, in millilitres; and
- whether the winged intravenous device is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 3 - Peripherally Inserted Central Catheters

A range of sterile peripherally inserted central catheters (PICCs) is required to meet clinical needs for adult, paediatric and neonatal patients.

Mandatory Criteria

PICCs shall:

- be flexible and radio-opaque;
- incorporate graduated markings in centimetres to assist with catheter positioning by indicating the position in the body**.**

Desirable Criteria

Preference will be given to multi-lumen PICCs that have the size of each individual lumen clearly printed on the external connector of each lumen.

Product Description

For each PICC offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- PICC:
  - open- or closed-ended;
  - material of construction (e.g. silicone, polyurethane);
  - diameter, in French gauge;
  - length, in centimetres;
  - length of taper, in centimetres
  - number of lumens;
  - trimmable or non-trimmable;
  - integral access ports (where applicable);
  - type of securement (e.g. adhesive, suture);
  - type of clamps (where applicable);
- guidewire (where applicable):
  - diameter, in
    - millimetres;
    - French gauge;
  - length, in centimetres.
- a list of kit contents and component dimensions.

Additional Information

For each PICC offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- whether the size and position of individual lumens is clearly labelled on the external connector of each lumen;
- insertion technique required (e.g. modified Seldinger or peel-away cannula);
- whether the PICC is recommended for use under hyperbaric pressure, and if so:
  - the recommended pressure rating in atmospheres (atms).
- whether the PICC is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second.
  - the recommended number of power injections.

- whether the PICC is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 4 - Central Venous Catheters and Guidewires

A range of sterile central venous catheters and guidewires is required to meet clinical needs for adult, paediatric and neonatal patients.

Mandatory Criteria

Central venous catheters shall:

- be radio-opaque;
- have centimetre markings along the distal portion of the catheter to facilitate accurate measurement of the depth of insertion.

Desirable Criteria

Preference will be given to multi-lumen central venous catheters that have the size of each individual lumen clearly printed on the external connector of each lumen.

Product Description

For each central venous catheter offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- catheter:
  - size, in French gauge;
  - length, in centimetres;
  - number of lumens (e.g. single, triple);
  - type of coating:
    - plain;
    - antimicrobial;
    - antibiotic.
    - location of coating-internal, external or impregnated
- guidewire (where applicable):
    - diameter, in
      - millimetres;
      - French gauge;
    - length, in centimetres.
- a list of kit contents and component dimensions.

Additional Information

For each central venous catheter, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging.
- maximum flow rate for rapid infusion catheters, in millilitres per minute.
- whether the central venous catheter is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second.
  - the recommended number. of power injections
- whether the size and position of individual lumens is clearly labelled on the external connector of each lumen.
- whether the central venous catheter is:
    - MRI safe, conditional or not safe
    - lipid compatible
    -

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 5 - Gravity Intravenous Administration Sets

A wide range of sterile, needleless luer access, luer lock, kink-resistant administration sets is required for gravity infusion of intravenous fluids, blood and blood products including lines used primarily in the anaesthetic environment.

Product Description

For each gravity intravenous administration set offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- type of set:
  - blood/solution, solution or universal (defined as used for solutions or blood);;
  - primary or secondary;
  - single- or double-spiked; and
  - vented or non-vented.
- tubing:
  - microbore or macrobore;
  - diameter, in millimetres;
  - length, in centimetres;
  - flow rate, in millilitres per minute;
  - tint colour (where applicable) (e.g. amber); and
  - type of luer lock connectors:
    - fixed or rotating;
    - male or female.
- integral set components (where applicable):
  - integral hand pump;
  - integral burette;
  - integral access ports:
    - open or closed luer access;
    - for closed luer access, brand name;
    - number of ports;
    - distance from the patient connection, in centimetres;
    - position (i.e. proximal or distal).
- where applicable, other set components:
  - blood filters;
  - anti reflux valves
  - roller clamps for flow control.
  - side-arm

Additional Information

For each gravity intravenous administration set offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- filter pore size in microns (where applicable);
- drops per millilitre; and
- priming volume in millilitres
- whether the gravity intravenous administration set is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 6 - Burettes

A wide range of sterile, needleless luer access burettes is required for the administration of intravenous therapy.

Mandatory Criteria

All burettes offered shall include graduation measurements.

Product Description

For each burette offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- burette:
  - volume, in millilitres.
  - extension tubing:
    - diameter, in millimetres;
    - length, in centimetres;
    - position (i.e. proximal or distal); and
    - type of clamps (e.g. slide, pinch, roller).

- micro-dropper chambers (where applicable); and
- type of shut-off valves (where applicable).
- cap or clamp on air inlet filter
- vented or non-vented.

Additional Information

For each burette offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- whether a hanger is present;
- the scale of graduations (e.g. 0.1 millilitres); and
- whether the burettes administration set is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.
Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 7 - Intravenous Extension Tubing

A wide range of completely sterile, luer lock, kink-resistant intravenous extension tubing is required for the administration of intravenous therapy.

Tenderers note

This category includes extension tubing only. All other extension set configurations are presented in **Error! Reference source not found.**.

Product Description

For each intravenous extension tube offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- tubing:
  - microbore or macrobore;
  - diameter, in millimetres;
  - length, in centimetres;
  - type of clamps (where applicable) (e.g. slide or pinch);
  - tint colour (where applicable) (e.g. amber);
  - type of luer lock connectors (where applicable):
    - fixed or rotating;
    - male or female.

Additional Information

For each intravenous extension tube offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- priming volume, in millilitres;
- whether the intravenous extension tube is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second; and
  - the recommended number of power injections
- whether the intravenous extension tube is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 8 - Intravenous Extension Sets

A wide range of sterile, needleless luer access, luer lock, kink-resistant extension sets is required for the administration of intravenous therapy.

Tenderers please note that the closed system transfer devices should be tendered under category 19.

Product Description

For each intravenous extension set offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- tubing:
  - microbore or macrobore;
  - diameter, in millimetres;
  - length, in centimetres;
  - type of clamps (where applicable) (e.g. slide or pinch); and
  - type of luer lock connectors:
    - fixed or rotating;
    - male or female.
- set components, for example:
  - anti-reflux valves (where applicable);
  - side-arms (where applicable);
  - access ports:
    - open or closed luer access;
    - for closed luer access, brand name;
    - number of access ports;
    - distance from the patient connection, in centimetres; and
    - position (i.e. proximal or distal).
    - integral filters in microns.

Additional Information

For each intravenous extension set offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- priming volume, in millilitres;
- whether the intravenous extension set is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second;
  - the recommended number of power injections
- whether the intravenous extension set is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/ Amiodarone

Category 9 - Multi-flow Adaptors

A wide range of completely sterile, needleless luer access, luer lock multi-flow adaptors is required for the administration of intravenous therapy.

Desirable Criteria

Preference will be given to multi-flow adaptors where each limb of the multi-flow adaptor incorporates a clamp that totally occludes fluid flow within the limb without damaging the tubing.

Product Description

For each multi-flow adaptor offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- tubing (where applicable):
  - number of limbs (e.g. two-way, three-way);
  - microbore or macrobore or both;
  - diameter, in millimetres;
  - length, in centimetres;
  - type of clamps (e.g. slide or pinch); and
  - type of luer lock connectors:
    - fixed or rotating;
    - male or female.
- other components (where applicable):
  - access ports:
    - open or closed luer access;
    - for closed luer access, brand name; and
    - number of access ports.
  - anti-reflux valves.
  - integral filters in microns.

Additional Information

For each multi-flow adaptor offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- priming volume, in millilitres;
- whether the multi-flow adaptor is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second;
  - the recommended number of power injections
- whether the multi-flow adaptor is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet

Tenderers are to state the required frequency for Intravenous line changes due to drug leaching/absorption into the plastic giving set. E.g. Administration of GTN/ Insulin/Amiodarone

Category 10 - Needleless Connectors

A wide range of sterile, closed luer access, luer lock needleless connectors is required for the administration of intravenous therapy.

Tenderers note

Intravenous access ports with extension tubing are to be tendered in **Error! Reference source not found.**.

Anti-reflux valves are included in this category.

Category 12: Pressure Displacement Valves has been incorporated in this category.

Product Description

For each needleless connector offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
  - type of mechanism (e.g. split septum ,mechanical or other)
    type of displacement (e.g. negative, neutral, positive)
  - type of luer lock connectors:
    - fixed or rotating
    - male or female
- additional components (where applicable) (e.g. caps).

Additional Information

For each needleless connector offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- priming volume, in millilitres;
- whether the needleless connector is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second.
  - The recommended number of power injections
- whether the needleless connector is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 11 - Intravenous Access Port Caps

A wide range of sterile, single & double-ended, luer lock intravenous access port caps is required for the administration of intravenous therapy.

Product Description

For each access port cap offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- colour;
- type of antimicrobial (if any); and
- percentage of antimicrobial.
- single or double-ended
- male or female

Additional Information

For each access port cap offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- whether the access port cap is:
    - MRI safe, conditional or not safe
    - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 12 - Stopcocks

A wide range of sterile, needleless luer access, multi-directional, luer lock stopcocks are required for the administration of intravenous therapy.

Product Description

For each stopcock offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- stopcock:
  - with or without extension tubing;
  - number of flow directions (e.g. two-way, three-way or four-way);
  - colour;
  - directional arrows or markers (where applicable);
  - type of luer lock connectors:
    - fixed or rotating;
    - male or female.
- extension tubing (where applicable):
  - microbore or macrobore;
  - diameter, in millimetres;
  - length, in centimetres;
  - anti-reflux valves (where applicable);
  - type of clamps (where applicable) (e.g. slide or pinch);
  - access ports (where applicable):
    - open or closed luer access;
    - for closed luer access, brand name;
    - number of access ports.

Additional Information

For each stopcock offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- priming volume, in millilitres;
- whether the stopcock is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second.
  - the recommended number of power injections
- whether the stopcock is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

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Category 13 - Port Access Needles

A wide range of sterile, non-coring port access needles is required for the administration of intravenous therapy.

Product Description

For each port access needle offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- safety or non-safety;
- with or without extension tubing;
- colour (to indicate size);
- needle:
  - gauge;
  - length, in millimetres;
  - profile (e.g. straight, right-angled).
- extension tubing (where applicable):
  - length, in centimetres;
  - diameter, in millimetres;
  - straight or Y-port;
  - access ports (where applicable):
    - brand name;
    - number of access ports.
- type of clamps (e.g. slide or pinch).

Additional Information

For each port access needle offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- whether the needle is high-profile or low-profile;
- whether the port access needle is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second;
  - the recommended number of power injections
- whether the port access needle is:
  - MRI safe, conditional or not safe
  - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

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Category 14 - Intravenous Catheter Fixation Devices

A range of sterile fixation devices is required to secure intravenous access devices.

Tenderers note

Intravenous transparent film dressings are in Category 21 IV Management. These are no longer available in the Wound Care Contract HPVC2015-027 contract.

Product Description

For each intravenous catheter fixation device offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- dimensions, in centimetres;
- device function (i.e. the type of device to be secured) (e.g. for PICC fixation); and
- fenestration (where applicable).
- mechanism of securement (e.g. invasive or adhesive)

Additional Information

For each intravenous catheter fixation device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- the names of brands with which the device is compatible.

The following information shall be readily available to all contract users in electronic format, at a minimum:

- the effects of temperature, humidity and perspiration on performance and adhesion;
- recommended duration of use; and
- any contraindications for use
- whether the intravenous catheter fixation device is:
    - MRI safe, conditional or not safe
    - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 15 - Antiseptic Skin Preparation Swab Stick, Wipes and Applicators

A range of skin preparation swab sticks, wipes and applicators is required for skin preparation for clinical procedures.

Mandatory Criteria

- All isopropyl alcohol items shall have a minimum strength of 70%;
- All chlorhexidine gluconate *without* alcohol items shall have a minimum strength of 2%;
- All chlorhexidine gluconate *with* alcohol items shall have a minimum strength of 0.5% chlorhexidine gluconate and a minimum strength of 70% alcohol;
- All povidone-iodine items shall have a minimum strength of 10%;
- Antiseptic skin preparation swab sticks, wipes and applicators shall be packaged in a manner that maintains the integrity of the contents.

Product Description

For each swab stick, wipe or applicator offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- sterile or non sterile;
- antiseptic concentration as a percentage (e.g. chlorhexidine gluconate 2%, isopropyl alcohol 70%, povidone-iodine 10%);
- swab stick, wipe or applicator dimensions (i.e. width and length), in millimetres;
- for swab sticks and applicators, stick length in millimetres;
- for wipes, one or two ply;
- where swab stick multi-packs are offered, number of swab sticks per pack.
- tint colour (where applicable)
- maximum surface area for preparation

Additional Information

For each swab stick, wipe or applicator offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging.

Category 16 - IV Start Kits

A range of sterile IV start kits is required for inserting intravenous access devices.

Mandatory Criteria

- All IV start kits shall be packaged in a peel pack that peels cleanly to expose the contents of the kit.
- Each IV start kit shall contain the following components as a minimum:
    - 1 x sterile plastic wrap;
    - 1 x chlorhexidine gluconate (with or without alcohol) wipe, swab stick or applicator;
    - 1 x transparent IV film dressing;
    - 2 x cotton woven (minimum two-ply) gauze wipes; and
    - 1 x fluid-resistant drape, at least 30 x 30 centimetres.

- Additional kit components may include:
    - 1 x disposable latex-free tourniquet;
    - 1 x pre-printed self-adhesive label to accommodate the date of insertion.

Product Description

For each IV start kit offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- list of kit contents, including:
    - concentration (as percentage) of chlorhexidine gluconate and alcohol (if applicable) contained in wipes, swab sticks or applicators,
    - widths and lengths in centimetres for:
        - plastic wrap;
        - wipes, swab sticks and applicators;
        - transparent film dressings;
        - cotton woven gauze wipes;
        - fluid-resistant drape;
        - self-adhesive labels;
        - latex-free tourniquets;
        - any other additional kit components not listed in the minimum requirements.

Additional Information

For each IV start kit offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging.
- Whether the swab sticks and applicators are inside or outside the inner pack

Category 17 - Non-Powered Ambulatory Infusion Devices

A range of non-powered ambulatory infusion devices is required to administer various medications in the hospital and home setting.

Desirable Criteria

Preference will be given to suppliers who provide carry bags free of charge.

Product Description

For each non-powered ambulatory infusion device offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- sterile or non-sterile.
- device:
  - elastomeric or spring loaded;
  - device capacity, in millilitres;
  - tubing length, in centimetres;
  - where filters are present, their position and function;
  - infusion duration in hours, days or minutes;
  - flow rate, in millilitres per hour;
  - a list of additional consumables required for the infusion device to function accurately (e.g. syringes, extension tubing, filters, catheterisation kit) including the dimensions of these consumables; and
  - a list of kit components (where applicable), including dimensions of each component.

Additional Information

For each non-powered ambulatory infusion device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging.
- filter size, in microns (where applicable).
- whether the device is:
  - capable of administering boluses;
  - refillable; (specify maximum number of uses)
  - MRI safe, conditional or not safe
  - lipid compatible.
- available accessories (e.g. carry bags and thermal pouches); and

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 18 - Closed System Transfer Devices

A range of completely sealed devices that mechanically prohibit the escape of hazardous drug, environmental (chemical and microbiological) or vapour concentrations outside the system throughout the entire process of dose preparation, administration and the handling of waste from hazardous drug therapy. Devices may include:

- devices to protect the handler from the vial/ampoule.
- devices to protect the operator during preparation.
- devices to protect the administrator during administration of the hazardous drug to the patient.

Criteria

- devices remain airtight (dry) and leak proof throughout all manipulations involved in the preparation, administration and disposing of hazardous drug doses.
- allow a closed system for intravenous, intramuscular and subcutaneous infusions and injections
- closed pressure equalisation to ensure there is no overpressure or vacuum when air or fluid is injected into or aspirated from the vial.

Product description

Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
- sterile or non-sterile.
- a list of additional consumables required for the closed system to function accurately (e.g. syringes, vial/bag spikes, extension tubing, access devices, filters, adaptors, ports/caps, etc.).

Additional information

For each device offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Sheet:

- compatibility with specific types of needleless access systems.
- compatibility with other chemotherapy compounding equipment and infusion devices such as ambulatory pump cassettes and non-powered ambulatory infusion devices.
- compatibility with specific infusion devices.
- compatibility with certain types of syringes.
- where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.
- the maximum recommended pressure rating (in PSI) of the connectors used for hazardous drug administration.
- The maximum recommended flow rate of the connectors used in hazardous drug administration.

Out of Scope

- Pharmaceutical products used in conjunction with CSTDs.
- Any use of CSTDs and associated consumables for pharmaceutical compounding by a third-party on behalf of a Participating Health Service.
- Any products consumables currently in an active HPV Contract.

Category 19 - Acute Haemofiltration Catheters

A range of sterile haemofiltration catheters for short-term use i.e. less than 4 weeks, to meet clinical needs of adult, paediatric and neonatal patients.

Criteria

Haemofiltration catheters shall:

- be radio-opaque.
- have a clamp on each separate lumen.
- priming volume (millilitres) indicated on each lumen.

Desirable criteria

- Multi-lumen haemofiltration catheters, with legible print on catheter extension detailing size (French gauge) and catheter volume (millilitres).
- Centimetre markings along the catheter to facilitate accurate measurement of the depth of insertion.

Product Description

For each haemofiltration catheter offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name
- catheter:
    - size, in French gauge;
    - length, in centimetres;
    - number of lumens (e.g. single, double, triple);
    - lumen configuration (e.g. coaxial)
    - priming volume of each lumen;
    - maximum flow rate and pressure reading at this flow rate;
    - extension type (e.g. straight extension, curved extension and pre-curved catheter legs);
    - material of construction (e.g. silicone, polyurethane);
    - type of coating, if any:
        - plain;
        - antimicrobial-coated;
        - antibiotic coated.
- guidewire (where applicable):
    - diameter, in:
        - millimetres;
        - French gauge;
    - length, in centimetres.
- where haemofiltration catheters are offered in kit form, a list of kit contents and component dimensions.

Additional Information

For each haemofiltration catheter offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging.
- maximum flow rate, in millilitres per minute and pressure at this flow rate.
- whether the size and position of individual lumens is clearly labelled on the external connector of each lumen and if individual lumens are colour coded.
- whether the haemofiltration catheter is:

- MRI safe, conditional or not safe
- lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Out of scope

Long-term haemodialysis catheters will not be considered.

Category 20 - **Intravenous Management**

A range of IV Management Dressings is required to meet clinical needs, including:

- a range of sizes in centimetres
- a moisture vapour permeability rate (MPVR) in grams/m²/24hours
- 3000 grams/m²/24 hours or whether the dressing has an incorporated label for insertion date

Respondents Note: Island Dressings incorporating a layer of transparent film and a layer of absorbent cotton padding or similar material are not required in this tender as they are currently included on HPVC2010-050 Surgical Dressings, Tapes and Bandages contract.

Category 21 - Midline Catheters

A range of sterile peripherally inserted midline catheters is required to meet clinical needs for adult, paediatric or neonatal patients.

Mandatory Criteria

Midline catheters shall:

- be flexible and radio-opaque;
- incorporate graduated markings in centimetres to assist with catheter positioning by indicating the position in the body**.**

Desirable Criteria

Preference will be given to midline catheters that have the size of each individual lumen clearly printed on the external connector of each lumen.

Product Description

For each midline catheter offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name.
    - material of construction (e.g. silicone, polyurethane);
    - diameter, in French gauge;
    - length, in centimetres;
    - Depth markers on catheter in centimetres
    - trimmable or non-trimmable
    - type of securement (e.g. adhesive, suture);
    - type of clamps (where applicable);
    - a list of kit contents and component dimensions.

Additional Information

For each Midline Catheter offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- insertion technique required (e.g. modified Seldinger or peel-away cannula);
- whether the midline catheter is recommended for use under hyperbaric pressure, and if so:
    - the recommended pressure rating in atmospheres (atms).
- whether the midline catheter is recommended for use with a power injector, and if so:
    - the recommended pressure rating, in PSI;
    - the recommended injection rate, in millilitres per second.
    - The maximum number of power injections.
- whether the midline catheter is:
    - MRI safe, conditional or not safe
    - lipid compatible.

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

Category 22 - Intraosseous Needles & Drivers

A wide range of sterile, Intraosseous needles is required for the administration of intravenous therapy.

Mandatory Criteria

Intraosseous driver:

- Powered driver must have a battery level indicator

Product Description

For each Intraosseous needle offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand name;
- manual or powered;
- with or without extension tubing;
- colour (to indicate size);
- needle:
  - gauge;
  - length, in millimetres;
- extension tubing (where applicable):
  - length, in centimetres;
  - diameter, in millimetres;
- type of clamps (e.g. slide or pinch).

Additional Information

For each intraosseous needle offered, Tenderers shall provide the following information in the relevant Additional Information columns of the Tender Response Worksheet:

- whether the product is marked as single-use on the external packaging;
- maximum flow rate, in millilitres per minute;
- whether the needle is high-profile or low-profile;
- whether the intraosseous needle is recommended for use with a power injector, and if so:
  - the recommended pressure rating, in PSI;
  - the recommended injection rate, in millilitres per second;
  - the recommended maximum number of power injections
- Intended patient weight (kg)

Where a drug incompatibility is known, Tenderers shall state the incompatible drug(s) in the relevant Additional Information columns of the Tender Response Worksheet.

For each intraosseous drivers offered, Tenderers shall provide the following information in the Product Description columns of the Tender Response Worksheet:

- brand Name
- model
- ARTG Number
- powered or non powered driver
- battery Type, e.g. NiCad, Li-Ion
- battery capacity; x Volts y AmpHour
- battery capacity; no. of insertions
- battery shelf-life
- battery replaceable
- a training unit should be available for powered drivers

E Appendices

Appendix 1 - Product List

Product Category	Product Subcategory
01- PERIPHERAL INTRAVENOUS CANNULAE	01.01 Peripheral IV cannula, safety
	01.02 Peripheral IV cannula, non-safety
02- WINGED INTRAVENOUS DEVICES	02.01 Winged Intravenous Devices, infusion set, safety, with tubing
	02.02 Winged Intravenous Devices, infusion set, non-safety, with tubing
03- PERIPHERALLY INSERTED CENTRAL CATHETERS	03.01 PICC, single lumen, polyurethane
	03.02 PICC, multiple lumen, polyurethane
	03.03 PICC, single lumen, silicone
	03.04 PICC, multiple lumen, silicone
	03.05 PICC, single lumen, for use with power injector
	03.06 PICC, multiple lumen, for use with power injector
04 - CENTRAL VENOUS CATHETERS AND GUIDEWIRES	04.01 Central Venous Catheterisation Kit, plain
	04.02 Central Venous Catheterisation Kit, antimicrobial-coated
	04.03 Central Venous Catheterisation Kit, Antibiotic Coated
	04.04 Central Venous Catheter and Central Venous Catheterisation Kit, guidewires (only)
	04.05 Central Venous catheter, plain, with power injector
	04.06 Central Venous Catheter Kit, for use with power injector
	04.07 Central Venous Catheter, antimicrobial – coated, with power injector
	04.08 Central Venous Catheter, antibiotic – coated, for use with power injector

05- GRAVITY INTRAVENOUS ADMINISTRATION SETS	05.01 Gravity Intravenous Administration Set, blood/solution, needleless luer access
	05.02 Gravity Intravenous Administration Set, blood/solution, needleless luer access, with integral hand pump, single spike
	05.03 Gravity Intravenous Administration Set, blood/solution, needleless luer access, with integral hand pump, double spike
	05.04 Gravity Intravenous Administration Set, solution, needleless luer access
	05.05 Gravity Intravenous Administration Set, solution, needleless luer access, with integral burette
	05.06 Gravity Intravenous Administration Set, safety, secondary infusion set
06- BURETTES	06.01 Burette, closed luer access
07- INTRAVENOUS EXTENSION TUBING	07.01 IV Extension Tubing, luer lock, macrobore
	07.02 IV Extension Tubing, luer lock, microbore
	07.03 IV Extension Tubing, luer lock, non-PVC
08- INTRAVENOUS EXTENSION SETS	08.01 IV Extension Set, needleless luer access
09- MULTIFLOW ADAPTORS	09.01 Multiflow Adaptor, needleless luer access
10- NEEDLELESS CONNECTORS	10.01 Needleless connector, negative displacement
	10.02 Needleless connector, neutral displacement
	10.03 Needleless connector, positive displacement
	10.04 Needleless connector, anti-reflux valves
11- INTRAVENOUS ACCESS PORT CAPS	11.01 IV Access Port Cap, double ended, male/female
	11.02 IV Access Port Caps, single-ended/double-ended, antimicrobial, male/female
12- STOPCOCKS	12.01 Stopcock, closed luer access
	12.02 Stopcock, closed luer access, with tubing
	12.03 Stopcock, open luer access
	12.04 Stopcock, open luer access, with tubing

	12.05 Stopcock, closed and open luer access
	12.06 Stopcock, closed and open luer access, with tubing
13- PORT ACCESS NEEDLES	13.01 Port Access Needle, safety, closed luer access, with extension tubing
	13.02 Port Access Needle, non-safety, closed luer access, with extension tubing
	13.03 Port Access Needle, safety, open luer access
	13.04 Port Access Needle, safety, open luer access, with extension tubing
	13.05 Port Access Needle, non-safety, open luer access
	13.06 Port Access Needle, non-safety, open luer access, with extension tubing
	13.07 Port Access Needle, powered, safety closed luer access, with extension tubing
	13.08 Port Access Needle, powered, safety, open luer access, with extension tubing
	13.09 Port Access Needle, powered safety, combination open & Closed Luer Access, with extension tubing
	13.10 Port Access Needle, safety, combination open and closed luer access, with extension tubing
	13.11 Port Access Needle, non-safety, combination open and closed luer access, with extension tubing
14- INTRAVENOUS CATHETER FIXATION DEVICES	14.01 IV Catheter Fixation Device
15- ANTISEPTIC SKIN PREPARATION SWAB STICKS, WIPES & APPLICATORS	15.01 Antiseptic Skin Preparation, isopropyl alcohol skin wipes
	15.02 Antiseptic Skin Preparation, chlorhexidine gluconate wipes
	15.03 Antiseptic Skin Preparation, chlorhexidine gluconate swab sticks, single or multi-packs

	15.04 Antiseptic Skin Preparation, chlorhexidine gluconate applicators, single or multi-packs
	15.05 Antiseptic Skin Preparation, chlorhexidine gluconate with alcohol wipes
	15.06 Antiseptic Skin Preparation, chlorhexidine gluconate with alcohol swab sticks, single or multi-packs
	15.07 Antiseptic Skin Preparation, chlorhexidine gluconate with alcohol applicators, single or multi-packs
	15.08 Antiseptic Skin preparation, povidone-iodine wipes, swab sticks, applicators
	15.09 Antiseptic Skin preparation, povidone-iodine & alcohol wipes, swab sticks, applicators.
16- IV START KITS	16.01 IV Start Kits with tourniquet
	16.02 IV Start Kits without tourniquet
17- NON-POWERED AMBULATORY INFUSION DEVICES	17.01 Non-Powered Ambulatory Infusion Devices
	17.02 Non-Powered Ambulatory Infusion Devices, kit
18 - CLOSED SYSTEM TRANSFER DEVICES	18.01 Closed System Transfer Devices, Vial spikes
	18.02 Closed System Transfer Devices, Bag spikes, with integrated infusion line
	18.03 Closed System Transfer Devices, Bag spikes only
	18.04 Closed System Transfer Devices, Connectors
	18.05 Closed System Transfer Devices, Infusion lines
	18.06 Closed System Transfer Devices, Seals
19 – ACUTE HAEMOFILTRATION CATHETERS	19.01Acute Haemofiltration Catheters
	19.02 Acute Haemofiltration Catheterisation Kits, plain

	19.03 Acute Haemofiltration Catheter, antimicrobial coated
	19.04 Acute Haemofiltration Catheterisation Kit, Antimicrobial coated
	19.05 Acute Haemofiltration Catheter, Antibiotic coated
	19.06 Acute Haemofiltration Catheterisation Kit, Antibiotic coated
20 – IV MANAGEMENT	20.01 Transparent Film Dressing, for Intravenous Site Management, with Antimicrobial
	20.02 Transparent Film Dressings, For Intravenous Site Management without Antimicrobial
21 – MIDLINE CATHETERS	21.01 Midline Catheter, single lumen, polyurethane
	21.02 Midline Catheter, multiple lumen, polyurethane
	21.03 Midline Catheter, single lumen, silicone
	21.04 Midline Catheter multiple lumen, silicone
	21.05 Midline Catheter, single lumen, for use with power injector
	21.06 Midline Catheter, multiple lumen, for use with power injector
	21.07 Accessories
22 – INTRAOSSEOUS NEEDLES & DRIVERS	22.01 Intraosseous Needles, manual
	22.02 Intraosseous Needles, powered
	22.03 Drivers for Intraosseous Needles

Appendix 2 - Australian and International Standards

The references to the below standards include any amendments, revisions or consolidations to those standards.

For each standard listed, Respondent are to ensure the latest publication of each standard is used.

Standard Number	Standard Name
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
National Standard 3– Preventing and Controlling Healthcare Associated Infections	National Safety and Quality Health Service Standards (NSQHSS) by Australian Commission on Safety and Quality in Health Care (ACSQHC).
AS1079.4	Packaging of items (sterile) for patient care. Part 4: Flexible Packaging Systems – for single use in hospitals.
ISO 13485	Medical Devices Quality Management System.
ISO 7864 / AS 1946	Sterile hypodermic needles for single use.

Guidelines and Other References

The references to the below guidelines include any amendments, revisions or consolidations to those guidelines.

- NHMRC (2010), Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia
- Therapeutic Goods Administration (1991), Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods
- Therapeutic Goods Administration (2004), Uniform Recall Procedure for Therapeutic Goods, Commonwealth of Australia.
- Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices.